IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: ZOSTAVAX (ZOSTER VACCINE : MDL NO. 2848

LIVE) PRODUCTS LIABILITY

LITIGATION

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THIS DOCUMENT RELATES TO:

: CIVIL ACTION NO. 18-md-2848

ALL CASES

:

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 340

Bartle, J. December 23, 2020

The Court has before it the multidistrict litigation involving cases alleging personal injuries caused by Zostavax, a vaccine for the prevention of shingles manufactured and sold by defendants Merck & Co., Inc. and Merck Sharp & Dohme Corp. (collectively "Merck"). Merck served in redacted form or has withheld from the Plaintiffs Executive Committee (the "PEC") several thousand documents over which it claims the attorney-client privilege. The PEC currently objects to Merck's privilege designations with respect to 43 such documents and moves to have the Court review the documents in camera, sustain the objections, and compel Merck to produce the documents.

Ι

The Court ordered Merck to submit the 43 documents for in camera review. Merck subsequently agreed to withdraw its privilege claims as to 21 of the documents without redaction.

The 22 documents that remain at issue are several e-mail chains

and attachments. In these e-mail exchanges, a number of Merck's employees, including counsel, discuss safety signals from a Zostavax clinical study and/or exchange proposed changes to a document entitled "Highlights of Prescribing Information."

Merck refers to the document as the Zostavax label.

The e-mail exchanges occurred in the context of comments Merck received from the Center for Biological Evaluation and Research ("CBER") on the Zostavax clinical study. The CBER is a division of the United States Food and Drug Administration. Merck maintains generally that the e-mails and attachments at issue contain legal advice or requests for legal advice which relate to the safety signals from the Zostavax clinical study and changes to the Zostavax label.

ΙI

The attorney-client privilege protects from compelled disclosure: (1) "communications"; (2) "between privileged persons"; (3) made "in confidence"; (4) "for the purpose of obtaining or providing legal assistance for the client." In reTeleglobe Commc'ns Corp., 493 F.3d 345, 359 (3d Cir. 2007). If the record is ambiguous as to whether the attorney-client privilege applies, the burden of proving it is on the asserting party. In re Grand Jury, 705 F.3d 133, 160 (3d Cir. 2012).

The purpose of the privilege is to "encourage full and frank communication between attorneys and their clients and

thereby promote broader public interests in the observance of law and administration of justice." <u>Upjohn Co. v. United</u>

<u>States</u>, 449 U.S. 383, 389 (1981). "The privilege recognizes that sound legal advice or advocacy serves public ends and that such advice or advocacy depends upon the lawyer's being fully informed by the client." Id.

The attorney-client privilege protects from disclosure not only the exchange of legal advice but also the information necessary to enable that advice. Upjohn, 449 U.S. at 391. In the case of a corporate client, the information necessary to enable counsel to provide sound legal advice is often possessed not by officers and agents responsible for directing a corporation's actions but by its lower-level employees. See id. at 391-92. Moreover, the advice of corporate counsel is frequently more significant to those employees who effectuate the client corporation's policies. See id. Consequently, consistent with the purpose of the attorney-client privilege, exchanges between the employees of a corporation and its counsel for the purpose of formulating legal advice are also protected from disclosure. See id. at 394.

Legal advice is often intertwined with and difficult to distinguish from business advice in the corporate community. Whether a document is protected from disclosure often depends on whether the communication at issue "is designed to meet problems

which can fairly be characterized as predominantly legal." In re Bristol-Myers Squibb Sec. Litig., Civil Action No. 00-1990, 2003 WL 25962198, at *5 (D.N.J. June 25, 2003) (emphasis original). The difficulty is exacerbated when reviewing the communications exchanged by in-house counsel who often perform the dual roles of legal advisor and business advisor. See Faloney v. Wachovia Bank, N.A., 254 F.R.D. 204, 209 (E.D. Pa. 2008).

Attorney-client privilege does not attach to a communication simply because it is between employees and corporate counsel. FTC v. Abbvie, Inc., Civil Action No., 2015 WL 8623076, at *9 (E.D. Pa. Dec. 14, 2015). Nor does it apply if a client seeks regulatory advice strictly for a business purpose. Id. The communication must be for the purpose of securing legal advice. Id. As this Court has stated previously, to find that in-house counsel was acting as a legal advisor the corporation asserting the attorney-client privilege must clearly demonstrate that the communication at issue was made for the purpose of securing legal not business advice. FTC v. Abbvie Inc., Civil Action No. 14-5151, 2016 WL 4478803, at *7 (E.D. Pa. Aug. 25, 2016).

III

The Merck e-mails and attachments at issue discuss

Zostavax label changes and potential safety issues in response

to comments of the CBER after a Zostavax clinical study. Such discussions in the highly regulated pharmaceutical industry often require the advice of counsel. We consider "the pervasive nature of governmental regulation" when "assessing whether the work of in-house attorneys in the drug industry constitutes legal advice." In re Vioxx Prod. Liab. Litig., 501 F. Supp. 2d 789, 800 (E.D. La. 2007). This does not, however, entitle Merck to a presumption that every e-mail exchange with its counsel or with which its counsel is involved is automatically protected by the attorney-client privilege. Id. at 800-01.

Many of the e-mails are sent to a dozen or more direct or copied recipients. One or more Merck in-house attorneys is among these recipients and occasionally authors an e-mail.

Merck does not specify the roles of these attorneys. It simply relies on their presence to support the contention that the e-mails are for predominantly legal purposes.

After careful review, all but one part of one of the e-mails appears to have been exchanged for predominantly business, pharmacological, or medical purposes. Sometimes the discussion revolves around grammar, punctuation or clarity.

Merck, except for the one part of one of the e-mails, has not met its burden to establish that the purpose of the e-mails was predominantly legal. See In re Grand Jury, 705 F.3d at 160.

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The one part of the one e-mail seeks legal advice and will be protected.